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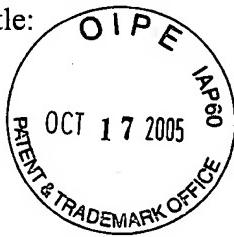
Applicant: Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Melissa Grace, Michael Slivka, Thomas G. Ferro, Vivek Shenoy, Alonzo D. Cook, and Scott Bruder

Application No.: 10/723,250 Group Art Unit: 1617

Filed: November 26, 2003 Examiner: Williams, Leonard M.

Confirmation No.: 6059

Title: LOCAL INTRAOSSEOUS ADMINISTRATION OF BONE FORMING AGENTS AND ANTI-RESORPTIVE AGENTS, AND DEVICES THEREOF



CERTIFICATE OF MAILING OR TRANSMISSION

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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
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Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- [ ] Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- [ ] No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- [ ] Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

[X] Enclosed herewith is form PTO-1449:

[X] Copies of the cited references, B1-B8 and C1-C42, are enclosed.

[X] Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

[ ] Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

[X] The listed references (A20, B7, B8 and C38-C42) were cited in the enclosed International Search Report in a counterpart foreign application.

[ ] The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

[ ] the explanation provided on the attached sheet.

[ ] the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ ] submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

[ ] the enclosed English language abstract.

[ X ] Applicant requests that the following pending applications be considered:

Examiner's  
Initials

— U.S. Patent Application No. 10/456,948, by Thomas M. DiMauro, Hassan Serhan, Mohamed Attawia, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins and John Siekierka, filed June 6, 2003, Docket No.: 3518.1012-001.

— U.S. Patent Application No. 10/610,355, by Hassan Serhan, Thomas M. DiMauro, Mohamed Attawia, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder and Gregory Collins, filed June 30, 2003, Docket No.: 3518.1012-002.

— U.S. Patent Application No. 10/631,487, by Thomas M. DiMauro, Hassan Serhan, Mohamed Attawia, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins, Laura J. Brown, Jeff Geesin, Pam Plouhar, Catherine Smith and John Siekierka, filed July 31, 2003, Docket No.: 3518.1012-003.

— U.S. Patent Application No.: 10/714,594 by Mohamed Attawia, Hassan Serhan, Thomas M. DiMauro, Melissa Grace and David Urbahns, filed November 14, 2003, Docket No.: 3518.1012-005.

— U.S. Patent Application No. 10/630,227, by Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Martin A. Reynolds, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins, Laura J. Brown, Jeffrey C. Geesin, Pamela L. Plouhar, Catherine Smith and John Siekierka, filed July 30, 2003, Docket No.: 3518.1015-000.

— U.S. Patent Application No. 10/640,412, by Mohamed Attawia, Thomas M. DiMauro, Hassan Serhan, Melissa Grace, Sudhakar Kadiyala, David Urbahns, Scott Bruder, Gregory Collins, Laura J. Brown, Jeff Geesin, Pamela L. Plouhar, Catherine Smith and John Siekierka , filed August 13, 2003, Docket No.: 3518.1019-000.

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Examiner

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Date

- [ X ] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- [ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Deirdre E. Sanders  
Deirdre E. Sanders  
Registration No.: 42,122  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: October 13, 2005

PTO-1449 REPRODUCED

O I P INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION  
October 13, 2005  
(Use several sheets if necessary)

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RECEIVED  
U.S. PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO.  
3518.1024-000APPLICATION NO.  
10/723,250FIRST NAMED INVENTOR  
Thomas M. DiMauroFILING DATE  
November 26, 2003EXAMINER  
Williams, Leonard M.CONFIRMATION NO.  
6059GROUP  
1617

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	US 2003/0007972 A1	01-09-2003	Tobinick
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	A3	US 2002/0010471 A1	01-24-2002	Wironen <i>et al.</i>
	A4	5,270,300	12-14-1993	Hunziker
	A5	5,942,499	08-24-1999	Radomsky
	A6	5,510,370	03-24-1999	Hock
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	A15	5,225,538	07-06-1993	Capon <i>et al.</i>
	A16	6,541,477 B2	04-01-2003	Goehring <i>et al.</i>
	A17	5,965,583	10-12-1999	Beers <i>et al.</i>
	A18	5,728,396	03-17-1998	Peery <i>et al.</i>
	A19	US 2003/0069639 A1	04-10-2003	Sander <i>et al.</i>
	A20	US 2003/0207827 A1	11-06-2003	Boyle <i>et al.</i>

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED			ATTORNEY DOCKET NO. 3518.1024-000	APPLICATION NO. 10/723,250	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			FIRST NAMED INVENTOR Thomas M. DiMauro	FILING DATE November 26, 2003	
October 13, 2005  (Use several sheets if necessary)			EXAMINER Williams, Leonard M.	CONFIRMATION NO. 6059	GROUP 1617

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES      NO
	B1	WO 02/057240 A1	07-25-2002	Ortho McNeil Pharmaceutical, Inc.	
	B2	WO 91/02078	02-21-1991	Peptide Technology, Ltd.	
	B3	EP 0 218 868 A2	04-22-1987	New York Blood Center, Inc.	
	B4	EP 0 288 088 B1	10-26-1988	Teijin Limited	
	B5	WO 92/07076	04-30-1992	The Charing Cross Sunley Research Centre	
	B6	WO 93/16099	08-19-1993	Biopharm Gesellschaft Zur Biotechnologischen Entwicklung Von Pharmaka MBH	
	B7	WO 99/45923	09-16-1999	Fisher <i>et al.</i>	
	B8	EP 0 950 417 A2	02-15-1999	Pfizer Products Inc.	

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PTO-1449 REPRODUCED  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  October 13, 2005  (Use several sheets if necessary)		ATTORNEY DOCKET NO. 3518.1024-000	APPLICATION NO. 10/723,250
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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

C1	Pacifici, R., "Editorial: Cytokines, Estrogen, and Postmenopausal Osteoporosis-The Second Decade," <i>Endocrinology</i> , 139(6):2659-2661 (1998).
C2	Allali, F. et al., "Increase in Bone Mineral Density of Patients with Spondyloarthropathy Treated with Anti-Tumour Necrosis Factor $\alpha$ ," <i>Ann. Rheum. Dis.</i> , 62:347-349 (2003).
C3	Tobinick, E.L., "Targeted Etanercept for Treatment-Refractory Pain Due to Bone Metastasis: Two Case Reports," <i>Clin. Ther.</i> , 25(8):2279-2288 (2003).
C4	Biskobing, D.M., "Novel Therapies for Osteoporosis," <i>Expert Opinion Invest. Drugs</i> , 12(4):611-621 (2003).
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C6	Rodan, G.A. et al., "Therapeutic Approaches to Bone Diseases," <i>Science</i> , 289:1508-1514 (2000).
C7	Nakamura, K. et al., "Local Application of Basic Fibroblast Growth Factor into the Bone Increases Bone Mass at the Applied Site in Rabbits," <i>Arch. Orthop. Trauma Surg.</i> , 115(6):344-346 (1996).
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C10	Pederson, A.W. et al., "Thermal Assembly of a Biomimetic Mineral/Collagen Composite," <i>Biomaterials</i> , 24:4881-4890 (2003).
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C12	Kimble, R.B. et al., "The Functional Block of TNF but Not of IL-6 Prevents Bone Loss in Ovariectomized Mice," <i>J. Bone Min. Res.</i> , 12(6):935-941 (1997).

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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

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C16	"Hydrogels", <i>Encyclopedia of Polymer Science and Technology</i> , (Wiley and Sons, 2003).
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C21	Bringman, T.S. <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
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C23	Schall, T.J. <i>et al.</i> , "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).
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C26	Engelmann, H. <i>et al.</i> , "Two Tumor Necrosis Factor-Binding Proteins Purified from Human Urine," <i>J. Biol. Chem.</i> , 265(3):1531-1536 (1990).
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C32	Baker, D. <i>et al.</i> , "Control of Established Experimental Allergic Encephalomyelitis by Inhibition of Tumor Necrosis Factor (TNF) Activity Within the Central Nervous System Using Monoclonal Antibodies and TNF Receptor-Immunoglobulin Fusion Proteins," <i>Eur. J. Immunol.</i> , 24:2040-2048 (1994).
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C36	Pargellis, C., "Inhibition of p38 MAP Kinase by Utilizing a Novel Allosteric Binding Site," <i>Nature Structural Biology</i> , 9(4):268-272 (2002).
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C38	De Santis, A. and Buchman, A., "Current and Emerging Therapies in Osteoporosis," <i>Expert Opin. Pharmacother.</i> , 3(7):835-843 (2002).

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C39	Nakamura, K. <i>et al.</i> , "Stimulation of Endosteal Bone Formation by Local Intraosseous Application of Basic Fibroblast Growth Factor in Rats," <i>Rev. Rhum. [Engl. Ed.]</i> , 64(2):101-105 (1997).
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C41	Crandall, C., "Combination Treatment of Osteoporosis: A Clinical Review," <i>J. of Women's Health &amp; Gender-Based Medicine</i> , 11(3):211-224 (2002).
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